

Remarks

The Office Action dated December 29, 2005 has been reviewed, and the following remarks are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims. Upon entry of the instant amendment, claims 1-7, 9 and 16 are pending. Claims 1 and 16 are amended. Written support for the claim amendments is found throughout the specification and in the original claims, thus Applicants submit that no prohibited new matter has been added.

Summary of the Final Office Action

1. Claim 16 was objected to because the word "chloroplast" was misspelled.
2. Claims 1, 2-7, 9 and 16 were rejected under 35 U.S.C. 112 (second paragraph) as being indefinite.
3. Claims 1, 2, 7, 9 and 16 were rejected under 35 U.S.C. 102(b) as being anticipated by *Casterman I et al.*
4. Claims 1, 2, 5, 7, 9 and 16 were rejected under 35 U.S.C. 102(b) as being anticipated by *Casterman II et al.*
5. Claims 1, 3, 4, 7, 9 and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over any of *Magnuson et al.* or *Casterman I et al.* or *Casterman II et al.* in view of *Owen et al.*
6. Claims 1, 3, 5, 7, 9 and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over any of *Magnuson et al.*, *Casterman I et al.* or *Casterman II et al.* in view of *Le Gall et al.*
7. Claims 1, 3, 6, 7, 9 and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over any of *Magnuson et al.*, *Casterman I et al.* or *Casterman II et al.* in view of *Artsaenko et al.*
8. Claims 1-7, 9 and 16 were provisionally rejected on the ground of non-statutory obviousness type double patenting as being unpatentable over claims 1-9 and 11-12 of copending Application No. 11/267,191.
9. Claims 1-7, 9 and 16 were provisionally rejected on the ground of non-statutory obviousness type double patenting as being unpatentable over claims 1-9 and 11-12 of copending Application No. 11/267,310.

Claim Objections

Claim 16 was objected to for allegedly containing a misspelling of the term chloroplast. Applicants have amended claim 16 to correct the spelling of "chloroplast" and therefore request that the objection to claim 16 be withdrawn.

Rejections under 35 U.S.C. 112 (second paragraph)

Claims 1, 2-7, 9 and 16 were rejected under 35 U.S.C. 112 (second paragraph) as being indefinite. Specifically, the Examiner purports that the recitation “said cellular compartment” in claim 1 (line 8) lacks antecedent basis.

Without acquiescing to the merits of the Examiner’s rejection and solely to advance prosecution of the pending application, Applicants have removed the phrase “said cellular compartment” from claim 1. Therefore, Applicants respectfully submit that the rejection of claim 1 and claims dependent thereon (claims 2-7, 9 and 16) under 35 U.S.C. 112 (second paragraph) is rendered moot.

Rejections under 35 U.S.C. 102(b)

The rejection of claims 1, 2, 7 and 9 was maintained and claim 16 was newly rejected under 35 U.S.C. 102 (b) as being anticipated by Casterman *et al.* I (WO 94/04678) (Casterman I). Specifically, the Examiner alleged that the previous amendment to the preamble of claim 1 to recite “producing in a plastid” did not overcome the rejection, as the preamble only states an intended use of the claimed method. Applicants respectfully traverse this rejection.

However, without acquiescing to the merits of the Examiner’s rejections, and solely for the purpose of advancing prosecution of the instant application, Applicants have amended claim 1 to recite that the claimed method encompasses the use of a nucleic acid which encodes a peptide which directs expression to the plastid in a plant. Casterman I neither expressly nor implicitly discloses the expression of heavy chain immunoglobulins in a plastid. Therefore, Applicants respectfully request that the rejection of claim 1 and claims dependent thereon (claims 2, 7, 9, and 16) be reconsidered and withdrawn.

Additionally, the rejection of claims 1, 2, 5, 7 and 9 was maintained and claim 16 was newly rejected under 35 U.S.C. 102 (b) as being anticipated by Casterman *et al.* II (U.S. Patent No. 5,759,808) (Casterman II). Specifically, the Examiner alleged that the previous amendment to the preamble of claim 1 to recite “producing in a plastid” did not overcome the rejection, as the preamble only states an intended use of the claimed method. Applicants respectfully traverse this rejection.

Applicants again note that amended claim 1 recites that the claimed method produces a functional heavy chain antibody or active fragment thereof in a plastid of a plant. Casterman II neither expressly nor implicitly discloses the expression of heavy chain immunoglobulins in a plastid. Therefore, Applicants respectfully request that the rejection of claim 1 and claims dependent thereon (claims 2, 5, 7, 9, and 16) be reconsidered and withdrawn.

Rejections under 35 U.S.C. 103(a)

Claims 1, 3, 4, 7, 9 remained rejected and claim 16 was newly rejected under 35 U.S.C. 103(a) as being unpatentable over any of Magnuson *et al.* (Protein Expression and Purification (1996) 7, 220-228) (Magnuson), Casterman I or Casterman II in view of Owen *et al.* (Biotechnology (1992) 10, 790-794) (Owen). Applicants respectfully traverse the rejection.

Without acquiescing to the merits of the Examiner's rejection, and solely for the purpose of advancing prosecution of the instant application, Applicants have amended claim 1 to recite that the claimed method encompasses expression of a functional heavy chain antibody or active fragment thereof in a plastid of a plant. Importantly, Magnuson, Casterman I, Casterman II or Owen neither teach nor suggest producing immunoglobulins in the plastid of a plant. In fact, the cited references teach away from the present invention as they indicate that an endoplasmic reticulum targeting sequence is necessary to produce functional antibodies in plants. Therefore, Applicants respectfully request that the rejection of claims 1, 3, 4, 7, 9 and 16 under 35 U.S.C. 103(a) be reconsidered and withdrawn.

Claims 1, 3, 5, 7, 9 remained rejected and claim 16 was newly rejected under 35 U.S.C. 103(a) as being unpatentable over any of Magnuson, Casterman I or Casterman II in view of Le Gall *et al.* (Applied and Environmental Microbiology (1998) 64, 4566-4572) (Le Gall). Applicants respectfully traverse the rejection.

Without acquiescing to the merits of the Examiner's rejections, and solely for the purpose of advancing prosecution of the instant application, Applicants have amended claim 1 to recite that the claimed method encompasses expression of a functional heavy chain antibody or active fragment thereof in a plastid of a plant. Concerning Magnuson, Casterman I and Casterman II, please refer to the above arguments. Also, Le Gall specifically indicates that their vector contained the leader sequence pelB which would express the scFv through the secretory (ER) pathway. Importantly, Le Gall neither teaches nor suggests expressing immunoglobulins in the plastid of a plant. In fact, Le Gall teaches away from the instant invention as it suggests that an endoplasmic reticulum targeting sequence is necessary to produce functional antibodies in plants. Therefore, Applicants respectfully request that the rejection of claims 1, 3, 5, 7, 9 and 16 under 35 U.S.C. 103(a) be reconsidered and withdrawn.

Claims 1, 3, 6, 7, 9 remained rejected and claim 16 was newly rejected under 35 U.S.C. 103(a) as being unpatentable over any of Magnuson, Casterman I or Casterman II in view of Artsaenko *et al.* (The Plant Journal (1995) 8, 745-750) (Artsaenko). Applicants respectfully traverse the rejection.

Without acquiescing to the merits of the Examiner's rejections, and solely for the purpose of advancing prosecution of the instant application, Applicants have amended claim 1 to recite that the claimed method encompasses expression of a functional heavy chain antibody or active fragment thereof

in a plastid of a plant. Concerning Magnuson, Casterman I and Casterman II, please refer to the above arguments. Also, Artsaenko employed an ER targeting sequence as well as a KDEL retention sequence in order to express and maintain an immunoglobulin in the ER. Importantly, Artsaenko neither teaches nor suggests producing immunoglobulins in the plastid of a plant. In fact, Artsaenko teaches away from the instant invention as is suggests that an endoplasmic reticulum targeting sequence is necessary to produce functional antibodies in plants. Therefore, Applicants respectfully request that the rejection of claims 1, 3, 6, 7, 9 and 16 under 35 U.S.C. 103(a) be reconsidered and withdrawn.

Non-Statutory Obviousness-Type Double Patenting Rejections

Claims 1-7, 9 and 16 were provisionally rejected on the ground of non-statutory obviousness type double patenting as being unpatentable over claims 1-9 and 11-12 of copending U.S. Patent Application No. 11/267,191.

Without acquiescing to the propriety of this rejection, Applicants respectfully point out that this is a provisional obviousness-type double patenting rejections between two applications. MPEP 804 (I)(B) (page 800-19) states,

If the “provisional” double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the “provisional” double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

With the amendments made to claim 1 in addressing the above rejections under 35 U.S.C. 102(b), 35 U.S.C. 112 (second paragraph) and 35 U.S.C. 103(a), Applicants submit that MPEP 804.I.B applies. Accordingly, withdrawal of the double patenting rejection is respectfully requested.

Additionally, claims 1-7, 9 and 16 were provisionally rejected on the ground of non-statutory obviousness type double patenting as being unpatentable over claims 1-9 and 11-12 of copending U.S. Patent Application No. 11/267,310.

Without acquiescing to the propriety of this rejection, Applicants respectfully point out that this is a provisional obviousness-type double patenting rejection between two applications and that MPEP 804 (I)(B) (page 800-19) also applies in this instance as well. With the amendments made to claims 1 and 16 in addressing the above rejections under 35 U.S.C. 102(b), 35 U.S.C. 112 (second paragraph) and 35 U.S.C. 103(a), Applicants submit that MPEP 804.I.B applies. Accordingly, withdrawal of the double patenting rejection is respectfully requested.

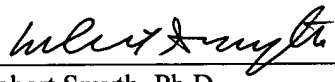
Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, they are invited to telephone the undersigned at their convenience.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: **June 29, 2006**
Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
202-739-3000

Respectfully submitted,
Morgan, Lewis & Bockius LLP


Robert Smyth, Ph.D.
Registration No. 50,801